



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/016,159	01/30/98	LEE	J 07004-002002

EXAMINER

PM11/1209
FISH & RICHARDSON P.C., P.A.
80 SOUTH SIXTH STREET
SUITE 3300
MINNEAPOLIS, MN 55402

ART UNIT	PAPER NUMBER
1646	4

DATE MAILED: 12/09/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-7 is/are pending in the application.
- ☐ Of the above, claim(s) 1, 2, 4, 6, 7 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 3, 5 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-7 are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

NOTICE ... re Sequences

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

ST AVAILABLE COPY

1. Receipt of the preliminary amendment filed with the instant application (adding the § 120 priority claim) is acknowledged.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2, and 7, drawn to a fusion protein comprising a soluble erythropoietin (EPO) receptor fragment (sEPO-R) (classified in Class 530/subclass 350), a vector encoding it (435/320.1), and a method of using these to make sEPO-R (435/69.7).

II. Claims 3 and 5, drawn to an sEPO-R fragment (530/350) and an immunoassay composition comprising it (435/7.1).

III. Claim 4 and 6, drawn to an antibody specific for an EPO-R (530/387.1+) and an immunoassay composition comprising it (435/7.21).

The inventions are distinct, each from every other, for the following reasons.

Claims 1, 2, and 7 of Group I are linked by the inventive concept of utilizing a particular recombinant fusion protein to make an sEPO-R polypeptide. Inventions I and II are thus related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the sEPO-R of group II may be alternatively produced by expression of the protein *per se* in a suitable host organism.

The antibody of group III is related to the proteins of each of groups I and II inasmuch as the former will recognize either of the latter. However, these inventions are patentably distinct because the proteins have independent utility, for example, as reagents useful to purify EPO. Moreover, the antibodies may be prepared independently via immunization against the intact EPO-R or against cells expressing it.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art, as shown by their different classifications and because they would entail divergent searches of the research literature and consideration of unique issues of patentability, restriction for examination purposes as indicated is proper.

During a telephone conversation on 13 May 1998, Mark Ellinger made a provisional election without traverse to prosecute the invention of group II, claims 3 and 5. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1, 2, 4, 6, and

7 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to non-elected invention(s).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

3. Applicant has not complied with one or more conditions for receiving the benefit of the filing date of original application serial no. 08/106,815 under 35 U.S.C. § 120: the instant application must contain a specific reference to the parent application(s) in the specification. The statement introduced in the preliminary amendment claims benefit only to the immediate parent application, serial no. 08/876,227. If the benefit of any earlier filing date is desired, amendment is required in order that the specification make appropriate reference at the first sentence(s) to the appropriate prior application(s).

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 for the reason(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

Applicant is requested to return a copy of the attached Notice to Comply with the response to this action.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5 6. Claims 3 and 5 are rejected under 35 U.S.C. § 102(b) as clearly anticipated by D'Andrea *et al.* (U.S. Patent No. 5,378,808).

D'Andrea describes recombinant production and purification of extracellular domain ("secreted receptor") human EPO receptor polypeptides (abstract; cols. 17-21). Notwithstanding any difference between the method employed by the reference and that described in the instant application to make the soluble receptor polypeptide, the prior art product appears to meet all of the material and functional limitations of product claim 5. The reference also describes the use of western blots to detect the secreted receptor in the course of purification (col. 21, lines 13-21). The substrate containing transferred, bound sEPO-R polypeptide reasonably appears to meet all of the material and functional limitations of claim 5.

15 7. Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over D'Andrea *et al.* ('808).

As noted above in connection with the rejection under § 102, D'Andrea discloses a polypeptide corresponding to the extracellular domain of the EPO receptor. The reference does not exemplify the use of the polypeptide to bind to EPO

20 It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the secreted receptor polypeptide described by D'Andrea to make an affinity chromatography matrix capable of binding EPO because the reference teaches that it will be useful for such purpose (paragraph bridging cols. 6-7). The matrix so made would appear to meet all of the material and functional limitations of claim 5 because it could be used for the quantitation of anti-receptor antibodies. The claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone

(703) 308-3934

Fax

All formal papers

(703) 308-4242

Informal communications

(703) 308-0294

e-mail (note PTO policies below)

david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1 receptionists at (703) 308-0196.



DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

7 December 1998

Examiner Fitzgerald is generally available weekdays from 8 a.m. to 4 p.m. (Eastern). If he is not available to take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the supervisor for this Art Unit, Lila Feisee, may be reached at (703) 308-2731.

To facilitate the receipt and handling of fax communications, please —

- ♦ **Submit formal faxes only to the Fax Center at (703)308-4242.**
- ♦ **Label the fax cover page: "OFFICIAL", "DRAFT", "AFTER-FINAL", etc.**
- ♦ **Use letter size (8½ × 11) paper.**
- ♦ **Call the examiner when you send an urgent communication.**
- ♦ **Do not send a duplicate copy by mail or courier.**

Most official papers and all informal communications may be submitted to the PTO by fax. For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30.

Any Internet e-mail communications will be made of record in the application file. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.